

Remarks

Claims Amendments

Upon entry of the foregoing amendment, claims 1 and 69-116 are pending in the application, with claims 1 and 96 being the independent claims. Claims 69-116 are new. Claim 1 is amended herein. Support for amended claim 1 can be found, for example, at least on page 8, lines 8-10 and in Example 4 of the application as filed. The amendment to claim 1 adds no new matter and its entry is respectfully requested.

Support for new claims 69, 70, 97, and 98 can be found at least on page 8, lines 8-10, and in Examples 3 and 4. Support for new claims 71-77 and 99-102 can be found at least on page 14, lines 6-13 and on page 18, line 1, through page 19, line 5, of the application as filed. Support for claims 78-83 and claims 103-108 can be found in the specification at least on page 18, beginning at line 28 and extending through line 5 on page 19, and on page 37, lines 19-22. Support for claims 84 and 109 can be found at least on page 37, lines 9-12. Support for claims 85 and 110 can be found at least on page 18, lines 20-23. Support for claim 86 can be found, for example, at least on page 14, lines 27 -28. Support for claims 87-90 can be found at least in Examples 3 and 4 of the specification. Support for claims 91, 92, and 93 can be found on page 13, line 28- page 14, line 2 of the application as filed, as well as on page 22, line 7- page 24, line 2. Claims 94, 95, 115, and 116 find support at least in Example 1 and Table 1 of the specification. Newly added claims 96 and 111-114 find support at least in Examples 4, 7, 8, and 9.

These claims add no new matter and their entry is respectfully requested.

Rejections Under 35 U.S.C. §112, First Paragraph

Claim 1 stands rejected under 35 U.S.C. §112, First Paragraph for containing nonenabled subject matter for recitation of the phrases “obtaining a host cell” and “cultivating said host cell”. To expedite allowance of claims, claim 1 has been amended to include the phrases “obtaining a bacterial host cell” and “cultivating said bacterial host cell.” Applicants assert that, in order to expedite prosecution of this case and in accordance with the statement in the Office Action that the specification is enabling for making a polypeptide as claimed in the form of inclusion bodies using a bacterial host cell, claim 1 as amended is enabled.

Claim 1 also stands rejected for containing subject matter that was not described in the specification in such a manner as to convey to the skilled artisan that the inventor(s) had possession of the claimed invention for recitation of the phrases “obtaining a host cell” and “cultivating said host cell.” To expedite allowance of claims, claim 1 has been amended to include the phrases “obtaining a bacterial host cell” and “cultivating said bacterial host cell”. Applicants assert that claim 1 as amended meets the written description requirement.

Claim 1 was further rejected for failure to meet the written description requirement of 35 U.S.C. §112, First Paragraph in not being described in the specification in a manner that would demonstrate to the average artisan that the inventor(s) had possession of the invention for recitation of the term “inclusion partner protein”. The Office Action states: “said genus, broadly claimed, is only supported by a single species, namely bacterial thioredoxin, which *is insufficient to put the skilled artisan in possession* of all members of the genus. Since said genus is inadequately described [,] method of use of said genus, as claimed, is inadequately described as well.”

[emphasis added] Applicants disagree with these statements, and traverse the rejection of claim 1 under 35 U.S.C. §112, first paragraph, for recitation of the phrase “inclusion partner protein” for at least the following reasons.

First, Applicants point out that the specification does not disclose a ‘single species’ but actually discloses a large number of proteins for use as inclusion partners (recited in newly added claim 73) on page 18, lines 1-27 of the application as filed, demonstrating that the inventors indeed had possession of the use of a class of proteins characterized by their sequestration in inclusion bodies when expressed in cells. The specification also discloses methods for determining whether a gene construct with a putative inclusion partner protein induces the production of inclusion bodies in cells on page 19, lines 10-16.

In the second place, Applicants contend that the Office Action misinterprets the “possession” aspect of the written description requirement. The written description requirement does not require, as the Office Action states, that the specification put one of average skill in the art in possession of the invention; rather, possession of the invention relates to the conception of the inventor : “To satisfy the written description requirement, an *applicant* must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, *he or she was in possession of the invention*” [MPEP 2163.02] The MPEP also states that “the Examiner has the initial burden, after a thorough reading and evaluation of the content of the application of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims.” Applicants contend that the Office Action has not presented a case for why the skilled artisan, on careful reading of the specification which provides many examples of fusion partner proteins, would not believe that the inventor

was in possession of the claimed method using an inclusion partner protein. Applicants therefore contend that claim 1 as amended fulfills the requirement that the subject matter of the claims is described in the specification so as to convey to one skilled in the art that the inventor(s) had possession of the invention as claimed.

Applicants therefore assert that claim 1 as amended therefore meets the written description requirement and enablement requirement under 35 U.S.C. §112, first paragraph, and respectfully request withdrawal of the rejection.

Rejections Under 35 U.S.C. §102(b)

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by McCoy et al. (U.S. Patent No. 5,270,181). Claim 1 has been amended herein to include the step: “(c) incubating the first polypeptide with a protein-binding dye to bind the protein-binding dye to the first polypeptide”. Applicants assert that McCoy et al. does not disclose incubating a polypeptide with a protein-binding dye as recited in amended claim 1. Furthermore, McCoy et al. teaches away from producing polypeptides in inclusion bodies, but rather teaches methods for producing recombinant fusion proteins as soluble proteins to avoid some of the disadvantages of inclusion body-localized proteins (See McCoy et al., Col. 1, 30-35 and Col 1, 49-54). Thus, each and every claim element is not found in the cited reference, and the reference does not anticipate the invention of claim 1. Applications therefore respectfully request that the rejection of claim 1 under 35 U.S.C. §102 (b) be removed.

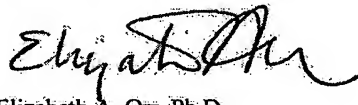
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Conclusion

Prompt and favorable consideration of this Amendment is respectfully requested. Applicants believe the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,



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